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Notice of Allowability	Application No.	Applicant(s)	
	10/628,670	QIAN, SUYUE	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to applicant's amendment filed 19 September 2006.
2. ☒ The allowed claim(s) is/are 1.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20061121</u> 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Suyue Qian on 15 November 2006.

The application has been amended as follows:

The title has been changed to: --Combining Transmittance Detection and Chromatographic Strip Techniques for Quantification of Analyte in Biological Fluids--.

Amendment to the claims submitted 4 March 2004.

Claim 1 has been changed as follows:

Claim 1. A method for detection of analytes in a biological fluid comprising:

- a) providing a dry test strip comprising:
 - a sample application well;
 - a reference cell and a detection cell;
 - a first passage connecting said sample application well to said reference cell;
 - a second passage connecting said sample application well to said detection cell;
 - an absorbent portion filled with absorbent material, said absorbent portion connected to said reference cell and said detection cell;
 - wherein each of said first and second passages are not in fluid communication with each other and each contains a material permeable to fluids and said permeable material in said first and second passages further includes a detection reagent;

- wherein said reference cell contains transparent beads and said detection cell contains transparent beads that are linked with binding partners that are capable of binding with the analyte, wherein the binding partners are selected from ligands, antibodies or antigens;
- b) placing a light source and detection unit on opposite sides of the test strip;
- c) contacting the biological fluid with the sample application well;
- d) allowing the biological fluid to flow through the first and second passageways to provide binding between the analytes and the binding partners in the detection region;
- e) detecting noise produced by said transparent beads in said reference cell by transmittance to provide a first signal;
- f) detecting binding produced by said analyte in said detection cell by transmittance to provide a second signal; and
- g) subtracting said first signal from said second signal thereby determining the amount of analyte in the biological fluid sample.

Claims 2-12 have been canceled.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: the prior art fails to teach a test strip comprising a reference and detection cell that are in fluid communication with a sample well, but not in fluid communication with each other, wherein the reference and detection cells each contain transparent beads with transmittance detection and the transparent beads in the detection cell comprising binding ligands specific for analyte. Blatt et al. (US 5,968,839) teach a test strip comprising detection and reference regions containing transparent material and transmittance detection of the test

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strip, but fail to teach the detection and reference regions not in fluid communication with each other, and transparent beads in the detection and reference regions. Pan et al. (US 2002/0192833) teach a test strip comprising detection and reference regions wherein transmittance detection is used to detect binding of analyte. However, Pan et al. fail to teach transparent beads in the measurement areas and a ligand attached to any material in the detection regions. Fish (US 2006/0110283) teaches an open detection well that is transparent and transmittance detection is used to detection analyte within the well. However, Fish fails to teach any ligand or reagent attached to transparent material within the detection well. Phelan (US 2005/0036148) teaches a transparent test strip used with transmittance detection having a reference and detection region, but fail to teach the material in the reference and detection region being transparent beads and the reference and detection region not being in fluid communication with each other.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Melanie Yu
Patent Examiner
Art Unit 1641



LONG V. LE 11/24/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600